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Patent  
Case No.: 57901US005

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Named Inventor: CLARKE, GRAHAM M.  
Application No.: 10/621620 Confirmation No.: 1875  
Filed: July 17, 2003 Group Art Unit  
Title: MICRONEEDLE DEVICES AND MICRONEEDLE DELIVERY APPARATUS

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**BRIEF ON APPEAL (AMENDED)**

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April 15, 2008	/Chris Johnson/
Date	Signed by: Chris Johnson

Dear Sir:

This is an appeal from the Office Action mailed on July 27, 2007, in light of the Advisory Action mailed July 27, 2007, finally rejecting claims 1-18.

Fees

- ☒ Any required fee under 37 CFR § 41.20(b)(2) will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.17 which may be required to Deposit Account No. 13-3723.
- ☒ Please charge any additional fees associated with the prosecution of this application to Deposit Account No. 13-3723. This authorization includes the fee for any necessary extension of time under 37 CFR § 1.136(a). To the extent any such extension should become necessary, it is hereby requested.
- ☒ Please credit any overpayment to the same deposit account.

A Notice of Appeal in this application was mailed on November 27, 2007, and was received in the USPTO on November 27, 2007.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

**REAL PARTY IN INTEREST**

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

**RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any related appeals or interferences.

**STATUS OF CLAIMS**

Claims 1-18 are pending, each of which has been finally rejected by the Examiner's action dated 07/27/2007, from which Appellant appeals. Claims 19-40 have been withdrawn from consideration.

The pending claims 1-18 are being appealed and may be found in the attached Claims Appendix.

**STATUS OF AMENDMENTS**

No amendments have been filed after the final rejection.

**SUMMARY OF CLAIMED SUBJECT MATTER**

The claims at issue concern microneedle drug deliver devices having one or more solid, tapered (e.g., pyramid shaped) microneedles with a truncated, flat tip. The term microneedle is defined in the description (page 7, first paragraph) as having a length of up to 500 micrometers. The flat tip reduces fractures of the microneedles, while still permitting penetration through the stratum corneum (page 2, lines 9-12).

There are four independent claims on appeal: 1, 8, 9, and 16.

Claim 1 calls for a microneedle device (10) comprising a substrate (20) comprising a first major surface (22); and at least one microneedle (30) projecting from the first major surface (22) of the substrate (20), the at least one microneedle (30) comprising a base (34) proximate the first major surface (22) of the substrate (20), wherein the at least one microneedle (30) is tapered from the base (34) to a solid flat tip (32) distal from the base (34) such that the at least one

microneedle (30) comprises a truncated tapered shape; wherein the solid flat tip (32) comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 250 square micrometers or less. See, e.g., specification page 2, lines 25-31, and page 7, line 13 to page 8, line 7.

Claim 8 is similar to claim 1 except that it requires each microneedle to be formed of one or more polymers (see specification page 3, line 8), the solid flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less, the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more (page 3, lines 11-13), and each microneedle of the plurality of microneedles aspect ratio of at least 3:1 (page 3, line 16).

Claim 9 calls for a microneedle device substantially as in claims 1 and 8, but the solid tip (32) is not required to be flat. The microneedle has a truncated tapered shape having a height (h) (see Fig. 2) above the first major surface (22) as measured from the base (34) to the tip (32), wherein the at least one microneedle (30) comprises a solid cross-sectional area of 20 square micrometers or more (page 3, line 23) and less than a base area of the at least one microneedle (page 3, line 24), where the solid cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of  $0.98h$  from the base (page 3, line 26; see Fig. 2).

Claim 16 calls for a plurality of microneedles formed of one or more polymers, tapered from the base to a solid flat tip with a solid cross-sectional area of 20 square micrometers or more and 25% or less of a base area of each microneedle of the plurality of microneedles (page 4, lines 3-4), where the solid cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of  $0.98h$  from the base (page 4, lines 5-6); wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more (page 4, line 7); and wherein each microneedle of the plurality of microneedles comprises a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more (page 4, lines 9-10).

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein.

Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

#### **GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

Claims 1-18 stand rejected under 35 USC § 102(e), as purportedly anticipated by Sherman et al. (US 2002/0020688).

#### **ARGUMENT**

The issue on appeal is straightforward: does Sherman et al. disclose truncated microneedles having a solid, flat tip of at least 20 square micrometers, as required by the present claims (or truncated tip as in claim 9)?

Applicants respectfully submit that Figure 11 of Sherman et al., relied upon by the Examiner, clearly does not disclose a solid microneedle structure. Moreover, where Sherman et al. does disclose solid microneedles they appear invariably to have conventional sharply pointed tips. For example, the Examiner cites paragraph 0088, but that paragraph actually supports Applicants' position (emphasis added):

**[0088]** Fig. 15A represents an alternative embodiment in which a microneedle array 290 comprises "solid" microneedles 292 and 294, rather than hollow microneedles as seen at 282 and 284 on FIG. 15. These solid microneedles 292 and 294 are formed by a similar mold as viewed on FIG. 12, but with the micropillars 222 and 224 removed from this mold, and a change in shape of the microholes 213 and 217. This simple change allows the solid microneedles to be formed within conical microholes (not shown on FIG. 12), and produces a pointed conical shape, as exhibited by the outer conical wall 250 and 252 for microneedle 292, with a top pointed surface at 296. Similarly, the microneedle 294 has a conical outer wall 254 and 256, with a similar top pointed surface at 298. The other dimensions and features of the solid microneedle array 290 can be exactly the same as those features of the hollow microneedle array 280 of FIG. 15, or the dimensions may be different since this is for a different application.

It is clear from this paragraph, as well as Figs. 15A, 24, 26, and 29, that Sherman et al. teaches only the conventional design of solid microneedles that are pointed at the tip, presumably based on the assumption in the art that this is preferable. However, as noted in the first paragraph on page 8 of the present specification, providing the microneedles with a blunt tip rather than pointed can improve structural integrity and avoid leaving fractured needle debris in the skin. This was not recognized or disclosed by Sherman et al.

Accordingly, Applicants believe that the present claims 1-18 are clearly novel over Sherman et al.

### **CONCLUSION**

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application and therefore request reversal.

Respectfully submitted,

April 14, 2008

Date

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**CLAIMS APPENDIX****Listing of Claims**

1. (Previously Presented) A microneedle device comprising:  
a substrate comprising a first major surface; and  
at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate, wherein the at least one microneedle is tapered from the base to a solid flat tip distal from the base such that the at least one microneedle comprises a truncated tapered shape;  
wherein the solid flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 250 square micrometers or less.
2. (Original) A device according to claim 1, wherein the at least one microneedle comprises a plurality of microneedles.
3. (Original) A device according to claim 1, wherein the flat tip comprises a surface area of 100 square micrometers or less.
4. (Original) A device according to claim 1, wherein the flat tip comprises a surface area of 50 square micrometers or less.
5. (Original) A device according to claim 1, wherein the at least one microneedle comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or more.
6. (Original) A device according to claim 1, wherein the at least one microneedle is formed of one or more polymers.
7. (Original) A device according to claim 1, wherein the base of the at least one microneedle comprises a base area of 900 square micrometers or more.

8. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

a plurality of microneedles projecting from the first major surface of the substrate, each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a solid flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein the solid flat tip comprises a surface area measured in a plane aligned with the base of 20 square micrometers or more and 100 square micrometers or less;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;

and wherein each microneedle of the plurality of microneedles comprises a height above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

9. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

at least one microneedle projecting from the first major surface of the substrate, the at least one microneedle comprising a base proximate the first major surface of the substrate, wherein the at least one microneedle is tapered from the base to a solid tip distal from the base such that the at least one microneedle comprises a truncated tapered shape having a height (h) above the first major surface as measured from the base to the tip;

wherein the at least one microneedle comprises a solid cross-sectional area of 20 square micrometers or more and less than a base area of the at least one microneedle, where the solid cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of 0.98h from the base.

10. (Original) A device according to claim 9, wherein the at least one microneedle comprises a plurality of microneedles.

11. (Previously Presented) A device according to claim 9, wherein the solid cross-sectional area comprises 25% or less of the base area.

12. (Previously Presented) A device according to claim 9, wherein the solid cross-sectional area comprises 100 square micrometers or less.

13. (Original) A device according to claim 9, wherein the at least one microneedle comprises a height (h) above the first major surface and a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 2:1 or more.

14. (Original) A device according to claim 9, wherein the at least one microneedle is formed of one or more polymers.

15. (Original) A device according to claim 9, wherein the base of the at least one microneedle comprises a base area of 900 square micrometers or more.

16. (Previously Presented) A microneedle device comprising:

a substrate comprising a first major surface; and

a plurality of microneedles projecting from the first major surface of the substrate, each microneedle of the plurality of microneedles comprising a base proximate the first major surface of the substrate, wherein each microneedle of the plurality of microneedles is formed of one or more polymers and is tapered from the base to a solid flat tip distal from the base such that each microneedle of the plurality of microneedles comprises a truncated tapered shape;

wherein each microneedle of the plurality of microneedles comprises a solid cross-sectional area of 20 square micrometers or more and 25% or less of a base area of each microneedle of the plurality of microneedles, where the solid cross-sectional area is measured in a plane aligned with the base, the plane being located at a distance of 0.98h from the base;

wherein the base of each microneedle of the plurality of microneedles comprises a base area of 900 square micrometers or more;



and wherein each microneedle of the plurality of microneedles comprises a maximum base dimension, the height and the maximum base dimension ratio defining an aspect ratio, wherein the aspect ratio is 3:1 or more.

17. (Original) A method of using a microneedle device, the method comprising:

- providing a microneedle device according to claim 1;
- contacting the skin on a patient with the at least one microneedle;
- forcing the microneedle device against the skin.

18. (Original) A method of using a microneedle device, the method comprising:

- providing a microneedle device according to claim 9;
- contacting the skin on a patient with the at least one microneedle;
- forcing the microneedle device against the skin.

19.-40. (Withdrawn)

**EVIDENCE APPENDIX**

None.

**RELATED PROCEEDINGS APPENDIX**

None.